

RECENS ULTRA - alcohol lotion
Certus Medical, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Recens Ultra 6365 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Ethyl Alcohol 62%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin, only when water is not available

Drug Facts Box OTC-Warnings Section

FLAMMABLE, keep away from fire and flames

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box OTC-Dosage & Administration Section

wet hands thoroughly with product and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredient Section

Water, Cetearyl Isononanoate, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, Glycerin, Ceteareth-12, Cetyl Palmitate, Carbomer, Diisopropylamine, Sodium Styrene/PEG-10 Maleate/Nonoxynol-10 Maleate/Acrylates Copolymer, Methylparaben, Propylparaben, fragrance, Tocopheryl Acetate, Aloe Barbadosis

Recens Ultra 6365 1000 ml



Recens Ultra

Hand Sanitizer with
Amino Lotion

*Contains
Vitamin E
and Aloe
Vera!*

**PACKAGED FOR USE IN
A WALL MOUNT DISPENSER**

DANGER: FLAMMABLE
KEEP OUT OF REACH OF CHILDREN
KEEP AWAY FROM FIRE OR FLAME
FOR EXTERNAL USE ONLY

Manufactured for Certus Medical, Inc.
P. O. Box 16247 Atlanta, GA 30321
www.certusmedical.com

1000 ML 33.8 FL. OZ.
6365M5PM.1108



Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 62%.....	Antiseptic

Use for hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

Flammable, keep away from fire and flames
For external use only

When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away

Directions ■ wet hands thoroughly with product and allow to dry without wiping

Inactive Ingredients Water, Cetearyl Isononanoate, Ceteareth-20, Cetearyl Alcohol, Glyceryl Stearate, Glycerin, Ceteareth-12, Cetyl Palmitate, Carbomer, Diisopropylamine, Sodium Styrene/PEG-10 Maleate/Nonoxynol-10 Maleate/ Acrylates Copolymer, Methylparaben, Propylparaben, fragrance, Tocopheryl Acetate, Aloe Barbadensis.

RECENS ULTRA
alcohol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75990-365
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER 1342 (UNII: 809Y72KV36)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIISOPROPYLAMINE (UNII: BR9JLI40NO)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75990-365-06	1 in 1 BOX		
1		800 mL in 1 BAG		
2	NDC:75990-365-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:75990-365-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:75990-365-01	1200 mL in 1 CARTRIDGE		
5	NDC:75990-365-03	350 mL in 1 CARTRIDGE		
6	NDC:75990-365-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:75990-365-07	700 mL in 1 BAG		
8	NDC:75990-365-09	2000 mL in 1 CARTRIDGE		
9	NDC:75990-365-10	1000 mL in 1 CARTRIDGE		
10	NDC:75990-365-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:75990-365-12	1000 mL in 1 BAG		
12	NDC:75990-365-13	800 mL in 1 BAG		
13	NDC:75990-365-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:75990-365-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:75990-365-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:75990-365-27	800 mL in 1 CARTRIDGE		
17	NDC:75990-365-55	208200 mL in 1 DRUM		
18	NDC:75990-365-08	1 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/28/2011	

Labeler - Certus Medical, Inc. (966433653)**Registrant** - ABC Compounding Co., Inc. (003284353)**Establishment**

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture